

K972967

**510(K) PREMARKET NOTIFICATION
SUMMARY OF SAFETY AND EFFECTIVENESS**

JAN 16 1998

**Osteonics® Scorpio™ Total Knee
Universal Dome and Recessed Patellar Components**

Submission Information

**Name and Address of the Sponsor
of the 510(k) Submission:**

Osteonics Corporation
59 Route 17
Allendale, NJ 07401-1677
201-825-4900

Contact Person:

Donna S. Wilson
Regulatory Affairs Specialist

Date Summary Prepared:

August 8, 1997

Device Identification

Proprietary Name:

Osteonics® Scorpio™ Total Knee Universal
Dome Patellar Component;
Osteonics® Scorpio™ Total Knee Recessed
Patellar Component

Common Name:

Knee Prosthesis

Classification Name and Reference:

Knee Joint, Patellofemorotibial,
Polymer/Metal/Polymer, Semi-
Constrained, Cemented Prosthesis
21 CFR §888.3560

Predicate Device Identification

The Osteonics® Scorpio™ Total Knee Universal Dome and Recessed Patellar Components are substantially equivalent to other legally marketed, Class II, patellar components, including the Osteonics® Scorpio™ Total Knee All-Polyethylene Patellar Components - concentric dome design, and the Johnson and Johnson® P.F.C.® Cruciate Sacrificing Patellar Component.

Device Description

The Osteonics® Scorpio™ Total Knee Universal Dome and Recessed Patellar Components are fabricated from ultra-high molecular weight polyethylene (UHMWPE). The articular geometry is designed with a round dome topography. The overall geometry essentially consists of a circular

patellar button configuration with three fixation pegs on the anterior surface of the component. The anterior surface of the components also features circular grooves and pockets for cement interdigitation. Each patellar component is available in 8mm and 10mm dome thicknesses.

Intended Use

The Osteonics® Scorpio™ Total Knee Universal Dome and Recessed Patellar Components are intended to articulate with any commercially available Osteonics® Scorpio™ Total Knee Femoral Component, any commercially available Osteonics® Series 7000 Total Knee Femoral Component, and any commercially available Osteonics® Omnifit® Total Knee Femoral Component. The subject patellar components are single use devices, intended for cemented application onto the surgically prepared posterior patella. These components replace the patellar articulating surface of the knee joint and simulate the natural function of the knee.

Statement of Technological Comparison

The Osteonics® Scorpio™ Total Knee Universal Dome and Recessed Patellar Components share the same materials, intended use, basic surgical techniques, and basic design features of their predicate devices. Applicable performance testing demonstrates that the subject devices perform at least as well as, if not better than, commercially available designs.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 16 1998

Robert A. Koch, J.D.
• Director, Regulatory/Legal Affairs
Osteonics Corporation
59 Route 17
Allendale, New Jersey 07401-1677

Re: K972967
Trade Name: Osteonics® Scorpio™ Total Knee Universal
Dome and Recessed Patellar Components
Regulatory Class: II
Product Code: JWH
Dated: November 13, 1997
Received: November 14, 1997

Dear Mr. Koch:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). This decision is based on this device being equivalent only to similar devices labeled and intended to be fixed within bone with acrylic "bone cement." You may, therefore, market your device subject to the general controls provisions of the Act and the following limitations:

1. This device may not be labeled or promoted for non-cemented use.
2. All labeling for this device, including package label and labeling ~~included within the package, must~~ prominently state that the device is intended for cemented use only.
3. Any non-cemented fixation of this device is considered investigational and may only be investigated as a significant risk device in accordance with the investigational device exemption (IDE) regulation under 21 CFR, Part 812. All users of the device for non-cemented fixation must receive approval from their respective institutional review boards (IRBs) and the Food and Drug Administration (FDA) to conduct the investigation.

The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practices, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal Laws or Regulations.

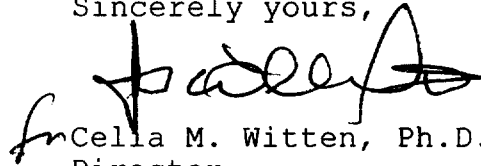
This letter will allow you to begin marketing your device as described in your 510(k) premarket notification immediately. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general -

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information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink, appearing to read 'C. Witten', with a stylized flourish at the end.

for Cella M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K 97-2967

Device Name: Osteonics® Scorpio™ Total Knee
Universal Dome and Recessed Patellar Components

Indications For Use:

The Osteonics® Scorpio™ Total Knee Universal Dome and Recessed Patellar Components are intended to articulate with any commercially available Osteonics® Scorpio™ Total Knee Femoral Component, any commercially available Osteonics® Series 7000 Total Knee Femoral Component, and any commercially available Osteonics® Omnifit® Total Knee Femoral Component. The subject patellar components are single use devices, intended for cemented application onto the surgically prepared posterior patella. These components replace the patellar articulating surface of the knee joint and simulate the natural function of the knee. The indications for the use of the Osteonics® Scorpio™ Total Knee Universal Dome and Recessed Patellar Components in conjunction with a total knee replacement, in keeping with those of other legally marketed Class II patellar components, are as follows:

Indications:

- Painful, disabling joint disease of the knee resulting from: degenerative arthritis, rheumatoid arthritis or post-traumatic arthritis.
- Post-traumatic loss of knee joint configuration and function.
- Moderate varus, valgus, or flexion deformity in which the ligamentous structures can be returned to adequate function and stability.
- Revision of previous unsuccessful knee replacement or other procedure.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

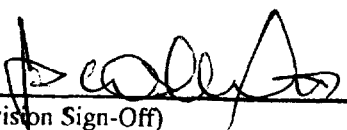
 Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
 (Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)


 (Division Sign-Off)
 Division of General Restorative Devices
 510(k) Number K972967